UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

№ 14-CV-4875 (RER)

N.K. AN INFANT BY HIS MOTHER AND NATURAL GUARDIAN,
TANJA BRUESTLE-KUMRA,

Plaintiff,

VERSUS

ABBOTT LABORATORIES,

Defendant.

OPINION & ORDER

May 22, 2017

RAMON E. REYES, JR., U.S.M.J,

Tanja Bruestle-Kumra ("Bruestle-Kumra") and her infant child N.K. (collectively "Plaintiffs") commenced this action against Abbott Laboratories ("Abbott") in May of 2014, alleging that Abbott failed to adequately warn of the teratogenic effects of its drug, Depakote, which caused N.K. to suffer from a constellation of severe birth defects. (Dkt. No. 1-2). Following removal to Federal Court and the close of discovery, Abbott moved for summary judgment pursuant to Fed. R. Civ. P. 56, on the grounds that: (1) Plaintiff had failed to offer admissible evidence regarding either specific causation or labeling deficiency; and (2) Plaintiffs' claim was precluded by federal law. (Dkt. No. 111). Intimately related to this motion are two of Abbott's pre-trial motions to exclude witness testimony on specific causation. (Dkt. Nos. 70, 84). Upon review of the proposed testimony and witness qualifications, I conclude that neither of the proffered witnesses may testify as to specific causation. Because Plaintiffs are incapable of offering any other admissible evidence on this required element of their claims, I find summary judgment appropriate and grant Abbott's motion.

BACKGROUND

Abbott produces and distributes Depakote, an anti-epileptic drug whose active ingredient, valproic acid, is a known teratogen linked to increased incidents of certain birth defects if taken during pregnancy. (Dkt. No. 1-2 ("Complaint") ¶ 4; Dkt. No. 1-3 ("Answer") ¶ 4; Dkt. No. 113 (Abbott's Rule 56.1 Statement ("Df. R.

56.1")) ¶ 23; Dkt. No. 116 (Plantiffs' Rule 56.1 Reply ("Pl. R. 56.1")) ¶ 23 (agreeing that Depakote was teratogenic but disputing the level of risk)). Plaintiffs contend that the warning label provided for Depakote was inadequate. (Complaint ¶ 14).

In mid-1997 Bruestle-Kumra suffered two seizures, resulting in her hospitalization. (Df. R. 56.1 ¶ 2; Pl. R. 56.1 ¶ 2). As a result of her seizures, Bruestle-Kumra was prescribed Depakote. (Df. R. 56.1 ¶ 3; Pl. R. 56.1 ¶ 3). She became pregnant in 2004, (Df. R. 56.1 ¶ 19; Pl. R. 56.1 ¶ 19), and continued taking Depakote throughout her pregnancy. (Df. R. 56.1 ¶14; Pl. R. 56.1 ¶ 14).

Bruestle-Kumra's son N.K. was born in March of 2005. (Df. R. 56.1 ¶ 19; Pl. R. 56.1 ¶ 19). N.K. suffers from a number of physical and developmental impairments including "cleft palate, hypospadias…, hypoplastic thumbs, micrognathia…, microcephaly, wide-set nipples, low-set ears, and facial dysmorphologies[,]" as well as a host of "cognitive developmental delays" and "autistic-like traits[.]"(Df. R. 56.1 ¶ 20; Pl. R. 56.1 ¶ 20). These wide-ranging and severe physical and mental injuries have caused great hardship for N.K. and his family and are the subject of this lawsuit. (Complaint). Plaintiffs allege that it was N.K.'s prenatal exposure to Depakote that caused his injuries, and they now seek just compensation. (Complaint).

DISCUSSION

I. Summary Judgment

1. Legal Standard

Abbott has moved for summary judgment, advancing several arguments including that Plaintiffs are unable to present evidence in support of each element of their claims. (Dkt. No. 111 (Memorandum in Support of Defendants Motion for Summary Judgment ("Df. MSJ Br.") at 4)).

Under Rule 56, the party seeking summary judgment bears the burden of proving that "there is no genuine dispute as to any material fact" and that it is "entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *see also Goenaga v. March of Dimes Birth Defects Found*, 51 F.3d 14, 18 (2d Cir. 1995). Where the nonmoving party "will bear the ultimate burden of proof at trial" the movant may satisfy its burden by "point[ing] to an absence of evidence to support an essential element of the nonmoving party's claim." *Goenaga*, 51 F.3d at 18; *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). If the movant satisfies its burden, it then falls to the nonmoving party to identify a genuine dispute of material fact that calls the movant's right to judgment into question. *United States v. Rem*, 38 F.3d 634, 643 (2d Cir. 1994). Doing so requires actual evidence in the form of "depositions, documents…or other materials[.]" Fed. R. Civ. P. 56(c)(1)(A); see also *Celotex Corp*., 477 U.S. at 324.

To prevail at trial, Plaintiffs must prove the element of causation by presenting "admissible expert testimony regarding both general causation, i.e., that [Depakote] exposure can cause the type of [injury suffered]; and specific causation, i.e., that [Depakote] exposure actually caused" N.K.'s injuries. *Amorgianos v. National R.R. Passenger Corp.*, 303 F.3d 256, 268 (2d Cir. 2002). Plaintiffs intend to meet their specific causation burden through the testimony of Dr. Rachel Lewis, M.D. ("Dr. Lewis") and Christopher Stodgell, Ph.D. ("Dr. Stodgell"). (Dkt. No. 114 (Memorandum in Opposition

to Summary Judgment ("Pl. MSJ Br.")) at 3-4).

Abbott has filed multiple motions *in limine* seeking to exclude witness testimony pursuant to Fed. R. Evid. 702 and *Daubert v. Merrell Dow Pharm. Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993). Among them are Abbott's motions to strike the specific causation testimony of Drs. Lewis and Stodgell. (Dkt. Nos. 70, 84). Absent this testimony Plaintiffs will be unable to meet their burden as to an essential element of their claims, entitling Abbott to judgment as a matter of law.[1]

2. Proposed Witnesses

Dr. Lewis is a pediatrician licensed to practice in New York. (Dkt. No. 88-2 (Affidavit of Dr. Lewis ("Lewis Aff.")) ¶¶ 1-2). She received her Medical Degree from Harvard Medical School and completed her residency at Morgan Stanley Children's Hospital of New York-Columbia University in 2003. (Lewis Aff. ¶ 3-5). She has been N.K.'s treating pediatrician since he was twelve days old. (Dkt. No. 88-3 (Deposition Testimony of Dr. Lewis ("Lewis Depo.")) 69:8-9).

Dr. Lewis has never conducted research on Depakote or valproic acid. (Lewis Aff.) Nor has she researched the effects of in utero exposure to valproic acid ("valproate exposure"). (Lewis Aff.). Prior to N.K.'s first visit, her knowledge of Depakote was limited to refilling prescriptions for epileptic patients. (Lewis Depo. 23:12-23). Since that initial visit, she has conducted little to no additional research on Depakote, valproic acid, or valproate exposure. (*Id.* 11:4-7, 23:3-7).

According to Dr. Lewis' expert report pursuant to Rule 26(a)(2), "[N.K.'s] condition is a result of his prenatal valproate exposure." (Lewis Aff. at 5).

Dr. Stodgell is an associate professor at the University of Rochester School of Medicine and Dentistry in the Obstetrics & Gynecology department. (Dkt. No. 74-1 (Dr. Stodgell's Expert Report ("Stodgell Report")) at 1). He has a B.A. in biology, a M.S. and Ph.D. in pharmacology and toxicology, and has received post-doctoral training in genetics. (*Id*; Dkt. No. 74-2 August Deposition Testimony of Dr. Stodgell ("Stodgell Depo.) 55:14). However, he is not a medical doctor. (*Id*.)

Dr. Stodgell's research focuses on teratology and autism; he is a member of the Teratology Society and is chair of the Autism Research Program. (Stodgell Report at 1). He has conducted extensive testing on the effect of in utero exposure to valproic acid on animals. (*Id.*) However, Dr. Stodgell has never conducted human testing and has never diagnosed valproate exposure in a human patient. (Stodgell Depo. 42:23-43:2).

It is Dr. Stodgell's opinion that N.K.'s injuries were caused by in utero exposure to valproic acid. (Stodgell Report 9-13).

II. Admissibility of Expert Testimony

1. Legal Standard

When a litigant seeks to introduce the opinion testimony of an expert witness, courts assume the active and important role of gatekeeper. *Daubert*, 509 U.S. at 589. In fulfilling this gatekeeper function, the Second Circuit requires courts to determine:

[1] To the extent that the expert report of Timothy Anderson, M.S., M.B.A., could be read as addressing specific causation, his testimony is inadmissible as he is unqualified to proffer a medical diagnosis. (Dkt. No. 77).

"(1) whether the witness is qualified as an expert to testify as to a particular matter, (2) whether the opinion is based upon reliable data and methodology, (3) whether the expert's testimony on the particular matter is relevant…and (4)" whether the proposed testimony complies with Fed. R. Evid. 403. *Glowczenski v. Taser Intern., Inc.*, No. 04-cv-4052 (SJF) (WDW), 2012 WL 976050, at *4 (E.D.N.Y. Mar. 22, 2012). If the expert cannot satisfy these requirements, their testimony must be excluded. *Nimely v. City of New York,* 414 F.3d 381, 396-97 (2d Cir. 2005). The party seeking to introduce expert testimony bears the burden of proving by a preponderance of the evidence that these requirements have been met. *United States v. Morgan*, ---Fed.Appx.---, 2017 WL 129902, at *1 (2d Cir. 2017).

2. Qualifications

Pursuant to Rule 702, "[a] witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion[.]" Fed. R. Evid. 702. The witness' qualifications do not need to be perfectly on point, and testimony is permitted where the witness' "educational and experiential qualifications in a general field closely related to the subject matter in question." *Davids v. Novartis Pharmaceuticals Corp.*, 857 F.Supp.2d 267, 276 (E.D.N.Y. 2012).

However, "[a]n expert, although generally qualified, may not be competent to render opinions under the circumstances of a particular case which are outside the expert's area of expertise." *Bourassa v. Black & Decker (U.S.) Inc.*, No. 12-CV-1476 (FJS/CFH), 2015 WL 4715250, at *3 (N.D.N.Y. Aug. 7, 2015). The court retains "the screening function traditionally played by trial judges[,]" *Nimely*, 414 F.3d at 395-9), and must determine whether "the expert [is] qualified to testify in the specific…or specialized area at issue." *Bourassa*, 2015 WL 4715250, at *3.

a) *Dr. Lewis*

Dr. Lewis is not qualified to testify that Depakote caused N.K.'s injuries. While undoubtedly qualified as an expert in general pediatric medicine, Dr. Lewis has no experience qualifying her to testify on the subject of specific causation. She has no training in teratology. (Lewis Depo. 23:2-6). She has never prescribed Depakote, only refilling prescriptions when her patient's prescribing doctors were unavailable. (*Id* at 23:12-23). Indeed there is no indication that she has any expertise, training, or experience that would qualify her to testify that Depakote was the cause of N.K.'s injuries.

Deficiencies in knowledge or experience may be overcome through "a review of other studies and scientific literature[, which] can be enough to qualify experts to testify and to make that proposed testimony reliable." *In re Mirena IUD Products Liability Litig.*, 169 F.Supp.3d 396, 412 (S.D.N.Y. 2016). There is no indication that Dr. Lewis conducted such research. Her familiarity with current medical literature on valproic acid and Depakote is limited to its use "in treating epileptic children." (Lewis Deop. at 23:24-24:7; 11:4-7 ("Q. In addition to your medical records, was there anything else you relied on in forming your opinion? A. In forming them, no."). Dr. Lewis did not perform any research or make any additional investigation that might qualify her as an expert on valproate exposure. (*Id* at 25:3-7). Her attempts to understand the cause of N.K.'s injuries were limited to a single review of a single medical book, the day of his first visit. (*Id* at 146:2-9). This is insufficient to qualify her as an expert and as such she may not testify to specific causation.

b) *Dr. Stodgell*

Dr. Stodgell has a more substantial background in the effects of valproate exposure. He is undoubtedly qualified to testify as to general causation, but just "because a witness qualifies as an expert with respect to certain matters or areas of knowledge, it by no means follows that he or she is qualified to express expert opinions as to other fields." *Nimely*, 414 F.3d at 399 n.13.

In the context of medical opinions, courts have consistently drawn a distinction between the qualifications of medical and non-medical doctors, noting that non-medical doctors who are qualified to diagnose a medical condition may be unable to reliably determine its cause. *Plourde v. Gladstone*, 69 Fed.Appx. 485, 487 (2d Cir. 2003) (Witness who was "a toxicologist and not a medical doctor" was not qualified to opine on specific causation in humans); *Coene v. 3M Co*., 303 F.R.D. 32, 55 (W.D.N.Y. 2014) ("Although a toxicologist may be qualified to testify as to causation, a toxicologist is generally not qualified to offer a medical diagnosis."); *Munafo v. Metropolitan Transp. Auth.*, No. 98-CV-4572 (ERK)(RLM), 00-CV-0134 (ERK)(RLM), 2003 WL 21799913, at *20 (E.D.N.Y. Jan. 22, 2003) (finding a phsychopharmocologist, who diagnosed and prescribed medication to treat conditions was not qualified to opine on the cause of said condition.").

As a teratologist and toxicologist, Dr. Stodgell may be qualified to testify that Depakote exposure can cause N.K.'s injuries. However, by his own testimony he has never evaluated children, has never been called upon to diagnose dysmorphic features or autism in a child, and is not a clinician. (Stodgell Depo. 42:23-44:14). His expertise is limited to the teratogenic effect of substances, such as valproic acid, in animals generally. (*Id*). This is insufficient to qualify him as an expert on the specific cause of N.K's injuries.

2. Methodology

Even if they possessed the necessary expertise, Drs. Lewis and Stodgell may not testify to specific causation because their opinions are not based upon reliable data and methodology, as required under Rule 702. *Glowczenski*, 2012 WL 976050, at *4. Courts are charged with "ensur[ing] that 'any and all scientific testimony or evidence admitted is not only relevant, but reliable.'" *Nimely*, 414 F.3d at 396 (quoting *Daubert*, 509 U.S. at 589). Rule 702 seeks to ensure reliability by requiring expert testimony to be "based on sufficient facts or data" and be "the product of reliable principles and methods" that "the expert has reliably applied[.]" Fed. R. Evid. 702.

Under the facts of this case, reliable methods require a differential diagnosis, in which doctors assess the patient's symptoms, create "a list of possible causes[,]" and then seek to eliminate possible causes "to identify the most likely cause[.]" *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 254 (2d Cir. 2005).

Courts have consistently found specific causation opinions reached without the aid of a differential diagnosis to be unreliable and requiring exclusion. *Israel v. Spring Industries, Inc.*, No. 98 CV 5106 (ENV)(RML), 2006 WL 3196956, at *10 (E.D.N.Y. Nov. 3, 2006) (Causation testimony "will satisfy *Daubert's* prerequisites for reliability only if the expert conducted a meaningful differential diagnosis ruling out other possible contributing factors."); *see also Davids*, 857 F.Supp.2d at 278 ("[E]ven though an expert

need not rule out every potential cause in order to satisfy *Daubert*, the expert's testimony must at least address obvious alternative causes and provide a reasonable explanation for dismissing specific alternate factors identified by the defendant.") (internal quotations omitted); *Glowczenski*, 2012 WL 976050, at *5 (listing additional factors courts consider, including "whether the expert has adequately accounted for obvious alternative explanations."); *Munafo*, 2003 WL 21799913, at*18 ("To the extent that [expert] testimony touches upon matters of causation, it will satisfy *Daubert's* prerequisites for reliability only if the doctor conducted a meaningful 'differential diagnosis' ruling out other possible contributing factors.").

a) *Dr. Lewis*

Plaintiffs argue that Dr. Lewis "arrived at her conclusion by using a differential diagnosis" because she initially determined that N.K.'s condition was either genetic or the result of valproate exposure and then eliminated the potential genetic causes. (Dkt. No. 87 (Plaintiff's Memorandum in Opposition to Motion to Strike the Testimony of Dr. Lewis ("Pl. Lewis Opp")) at 17). Plaintiffs are only partially correct. Dr. Lewis' records and deposition testimony confirm that she viewed N.K.'s condition as either genetic or the result of prenatal valproate exposure. (Lewis Depo. 145:13-20). However, it is clear that Dr. Lewis failed to adequately investigate or eliminate potential genetic causes before arriving at her opinion.

By Dr. Lewis' own admission, both in her deposition and her medical records, N.K.'s condition might have been caused by prenatal valproate exposure or have resulted from genetic factors. (Lewis Depo. 144:20-22, 145:13-20). Despite this, Dr. Lewis testified that immediately after N.K.'s first appointment she came to believe his injuries were caused prenatal valproate exposure. *Id* at 144:20-22). She reached this conclusion before eliminating any genetic causes, based only on a review of N.K.'s symptoms in a medical textbook – Smith's Congenital Human Malformations. *Id* at 146:2-9.

Not only did Dr. Lewis fail to eliminate alternative causes before reaching her initial conclusion, she lacked the knowledge to independently rule out genetic causes. She has no background in genetics and has never treated patients with the genetic disorders capable of causing N.K.'s constellation of injuries. (*Id* at 23:2-6, 62:6-10, 76:7-11). As such, her initial opinion was reached through improper methodology.

Subsequent to the formation of her opinion, additional but ultimately insufficient testing was conducted.

In 2005 N.K. was sent to Dr. Yebao, a geneticist, who ran tests for Pierre Robin, Smith-Lemli-Opitz ("Opitz"), DiGreorge, and Fanconi. (Dkt. No. 88-4 (Dr. Lewis' Notes on Phone Call With Dr. Yebao ("Yebao Call")); Stodgell Depo. 159:6-17). Following testing, Dr. Yebao informed Bruestle-Kumra and Dr. Lewis that N.K.'s results were normal, but he called for a "re-evaluation in Genetics in six months" to determine if any additional testing was warranted. (Dkt. No. 88-6; Dkt. No. 88-5 (Yebao Report) at 2). Dr. Lewis is not sure if this re-evaluation ever occurred. (Lewis Depo. 95:13-23). She did testify, however, that Dr. Yebao did not believe N.K.'s condition was the result of valproate exposure. (*Id* at 99:2-9; Yebao Call).

Dr. Lewis disagreed with this conclusion. (Lewis Depo. 81:15-18). However, she lacks the expertise to challenge

Dr. Yebao's assessment. With regard to Pierre Robin, she stated that the disorder was "not my area of expertise[.]" *Id* at 62:6-10. She has never treated a patient with Opitz or Fanconi. *Id* at 76:7-11. When asked if she was sure these causes had been ruled out, Dr. Lewis testified "DiGeorge, for sure. They did that specific FISH. And DiGeorge they did a specific test. Fanconi and Opitz, you would have to ask the geneticist….But I think it is implied by their testing." *Id* at 78:5-24.

In addition to Dr. Yebao's call for more testing, at least four other treating physicians have recommended further genetic testing to determine the cause of N.K.'s injuries.

In 2013 N.K. received a dermatological examination from Kimberly Morel, M.D. ("Dr. Morel"). (Dkt. No. 88-7 ("Morel Report") at 1). Dr. Morel recommended that N.K. be sent to Dr. Yebao to be tested for NF1. *Id* at 3. Dr. Lewis has no record of additional genetic testing following Dr. Morel's recommendation. (Lewis Depo. 113:23). She did not believe further testing was necessary as she disagreed with Dr. Morel's assessment that N.K. met the clinical criteria for NF1. (*Id* at 114:3-8).

In 2014 Dr. Murray Engel, M.D. ("Dr. Engel") provided Dr. Lewis with a report on N.K. in connection with reported staring spells. (Dkt. No. 86-4 ("Engel Report") at 1-2). Like Dr. Morel, Dr. Engel recommended further genetic testing for "the possibility of NF1 or other genetic diagnosis in addition to [N.K.'s] in utero exposure to anti-epileptic medication." *Id* at 7. According to Dr. Engel, Bruestle-Kumra declined further testing because she believed N.K.'s condition was the result of Depakote exposure. (*Id* at 6). Despite a second opinion citing NF1 as a potential cause, no additional genetic tests were ever conducted. (Lewis Depo. 124:8-23).

In 2015, John T. Wells, M.D. ("Dr. Wells") conducted a neurological evaluation of N.K. related to his academic difficulties. (Dkt. No. 86-5 ("Wells Report") at 5). Dr. Wells was aware of the original genetic testing, but in felt N.K. should "have a follow up genetics evaluation." (*Id* at 6).

Later that year N.K. was evaluated by Arthur Mandel, M.D. ("Dr. Mandel") for attention problems. (Dkt. No. 86-6 ("Mandel Report") at 2). Like Dr. Wells, Dr. Mandel stated that "genetics ha[ve] advanced and it may be helpful to see genetics again in order to get more advanced testing." (*Id* at 6). No further tests were performed and Dr. Lewis did not consult with a geneticist regarding the possibility of new testing. (Lewis Depo. 134:15-17).

Five doctors, including Dr. Yebao, recommended additional genetic testing at some point in N.K.'s treatment. Dr. Lewis, however, has conducted no additional testing. Rather, she has neglected to explore alternative potential causes such as NF1.

Dr. Lewis has also ignored improvements in genetic testing over the past decade which might yield more concrete results. As noted above, Dr. Yebao was unable to definitively determine causation and he, along with four other treating doctors, recommended renewed testing. However, when asked if improvements in genetic testing over the past decade might lead to more conclusive results, Dr. Lewis stated that "what they would add to a child I saw ten years ago who couldn't have had that test, I don't know. They are very specific genetic tests. I have never ordered them myself[.]" (*Id* at 48:17-25).

Still, Dr. Lewis "ha[s]n't reached the conclusion that genetic testing, more detailed, more recent…would come back normal." (*Id* at 149:6-9). Based on the lack of adequate results, she is unable to rule out genetic causes. (*Id* at 135:10-12) ("Q. Are you able to rule out a genetic underlying cause of NK's cognitive and physical disabilities?...A. If we must provide 'yes' or 'no answer, I guess I have to say no."). Despite her own admission that renewed testing might indicate genetic causes, she has made no effort to explore this possibility.

In addition to potential genetic factors, Dr. Mandel also referenced a possible structural brain lesion. (Mandel Report). Dr. Lewis could not testify as to any testing done to explore Dr. Mandel's concerns. (Lewis Depo. 132:21-133:7). She did reference an MRI conducted prior to Dr. Mandel's evaluation, but noted that it "might not be a perfect study" because of problems with the original test. (*Id* at 133:3-7). She was also unable to "make a conclusion" as to whether cerebral hemorrhaging was the cause of N.K.'s mental or emotional problems or whether it might be caused by valproate exposure. (*Id* at 160:7-12).

Dr. Lewis has not adequately explored or eliminated viable alternative causes. Because she failed to order tests necessary for an accurate diagnosis and did not apply reliable methods to assessing the limited information she did possess, Dr. Lewis' opinion is incapable of satisfying the requirements of Rule 702.

b) *Dr. Stodgell*

Dr. Stodgell did not conduct his own independent investigation. His opinion is based entirely on reviewing existing reports provided to him by Plaintiffs, such as that of Dr. Lewis. (Stodgell Depo. 40:4-12; Dkt. No. 74-9 (November Deposition Testimony of Dr. Stodgell ("Stodgell Depo. 2")) 41:17-19). Dr. Stodgell relied entirely on Plaintiffs' counsel to determine which records were relevant and which did not need to be provided or reviewed. (Stodgell Depo 2 41:22-42:3). It is also clear that he did not have access to all the relevant reports when he produced his expert report. (Stodegll Depo. 2 22:1-23:3) ("I saw those documents after I prepared my report" referring to multiple pediatric records and notes). As such, his report suffers from the same defects as Dr. Lewis'.

Further, a no time prior to forming his opinion did Dr. Stodgell view pictures or videos of N.K., personally examine N.K., or otherwise interview N.K. (*Id* at 36:4-14). Nor did Dr. Stodgell speak directly with any of N.K.'s treating doctors or relatives. (*Id* at 36:24-37:6). He also lacked key facts, like the results of N.K.'s MRI evaluation, which revealed hemorrhaging. (*Id* at 79:4-5). As a result, Dr. Stodgell does not possess adequate facts on which to base his causation opinion.

Nor did he apply proper methodology to the facts he did possess, failing to conduct a differential diagnosis. Dr. Stodgell's attempt to rule out potential alternative causes of N.K.'s condition is plagued by the same problems as Dr. Lewis'. He relied on Dr. Lewis' flawed report in ruling out genetic causes. (*Id* at 41:9-18) ("A. There was comment that genetic testing was done, chromosomal analysis and those were negative for known genetic defects or chromosomal abnormalities. So to me that was the major rule-out. Q. All right. Who was the geneticist…who ruled out genetic causes…A. This was a comment that was made in the medical record by the pediatrician[.]").While an expert witness may rely on the treating physician's reports and records, where the "treating

physicians…have not been shown to satisfy the requirements of Rule 702" the expert's testimony is deemed similarly flawed. *Mallozzi v. EcoSMART Technologies, Inc.*, No. 11-CV-2884 (SJF)(ARL), 2013 WL 2415677, at *13 n.8 (E.D.N.Y. May 31, 2013).

He did not consider other genetic causes because "[he] was under the assumption that genetic causes had been ruled out or were not being considered." (Stodgell Depo 163:3-7). Even if he had wanted to conduct a differential diagnosis, he could not have because he did not know which tests had been conducted and was unfamiliar with key genetics reports such as Dr. Yeboa's initial clinical notes or follow-up genetic summary. (*Id* at 42:18-19, 148:7-14, 158:7-159:8, 160:9-14).

Because he has relied on Dr. Lewis' flawed analysis and took no independent steps to conduct his own differential diagnosis, Dr. Stodgell's testimony does not satisfy the requirements of Rule 702.

III. Admissibility of Fact Witness Testimony

Plaintiffs argue that "since Dr. Lewis' opinion as to the cause of N.K.'s injuries was formed during the course of her treatment of N.K., such opinion testimony is considered factual in nature, and therefore not subject to *Daubert* exclusion." (Pl. Lewis Opp. at 15). Plaintiffs cite multiple cases in support of this proposition. (*Id.* at 16-17). Plaintiffs' cases focus on the fact verses expert distinction for the purpose of compliance with Fed. R. Civ. P. 26's disclosure requirements and payment of fees, not with motions to exclude testimony under Rule 702 and *Daubert*. e.g. *Puglisi v. Town of Hempstead Sanitary Dist. No. 2*, No. 11-CV-0445 (PKC) (GRB), 2013 (WL 4046263at *1 (E.D.N.Y. Aug. 8, 2013) ("Treating physicians may be treated as fact witnesses not required to provide an expert report[.]"); *Turner v. Detla Air Lines, Inc.*, No. 06 CV 1010 (NGG)(CLP), 2008 WL 222559, at *1 (E.D.N.Y Jan. 25, 2008) ("[I]f a treating physician is asked to render opinion testimony based on the physician's specialized skill and knowledge that falls within Federal Rule of Evidence 702, the treating physician may be entitled to an expert fee.").

However, "the testimony of a treating physician…is not without bounds," *Ali v. Connick*, No. 11-cv-5297 (NGG) (VMS), 2016 WL 3002403, at *7 (E.D.N.Y. May 23, 2016), and "treating physicians who are designated as non-retained experts…are not…permitted to render opinions outside the course of treatment and beyond the reasonable reading of the medical records." *Davids*, 857 F.Supp.2d at 280. Dr. Lewis testified that, during her treatment of N.K., she concluded that his condition was caused by valproate exposure. However, such a conclusion is not reflected in her medical records.

In her initial assessment, following N.K.'s first visit, Dr. Lewis wrote "? Valproate embryopathy" which she testified meant "possible valproic embryopathy[,]" but never expressly wrote that N.K.'s injuries were caused by Depakote or valproic acid. (Lewis Depo. 70:3-5, 161:7-24). She further testified that at that time she could not definitively determine that N.K.'s injuries were the result of valproate exposure. (*Id* at 70:12). In her subsequent reports she makes reference to valproate exposure, but consistently writes "unknown etiology." (*Id* at 99:2-100:6). The conclusion that N.K. was the victim of valproate exposure is simply not reflected in Dr. Lewis' medical records.

Even if such an opinion could be read into her records, classifying Dr. Lewis as a fact expert does not relieve this Court of its duty to ensure she utilized reliable methods in reaching her opinion. *Munafo*, 2003 WL 21799913, at *18 (*Daubert's* "requirements are not diminished merely because the expert witness is a 'treating physician' rather than an expert retained solely for the purposes of litigation."); *see also In re Zypreza Products Liability Litig.*, 489 F.Sup.2d 230, 282 (E.D.N.Y. 2007) (noting that fact witnesses may also be experts, subject to the requirements of Rule 702).

Courts in this district have found that "when [a] treating physician seeks to render an opinion on causation, that opinion is subject to the same standards of scientific reliability that govern the expert opinions of physicians hired solely for the purposes of litigation." *Davids*, 857 F.Supp.2d at 280 (internal quotations omitted); *see also Mallozzi*, 2013 WL 2415677, at *13 n.8 ("[T]he deficiencies in Dr. Levy's testimony cannot be overcome by his reliance upon causation opinions of plaintiff's treating physicians that have not been shown to satisfy the requirements of Rule 702."); *Deutsch v. Novartis Pharm. Corp.*, 768 F.Supp.2d 420, 472 (E.D.N.Y. 2011) (finding a treating physician's causation opinion to be limited by the reliability requirements of Rule 702).

For the reasons discussed above, Dr. Lewis' flawed methodology is unreliable. Therefore, she is unable to testify as to causation regardless of how Plaintiffs seek to characterize her.

CONCLUSION

For the reasons set forth above, Defendant's motions to strike the causation testimony of Drs. Lewis and Stodgell are GRANTED. As a result, they will be unable to testify that Bruestle-Kumra's use of Depakote during pregnancy caused N.K.'s injuries. Plaintiff can offer no other admissible evidence of specific causation. Therefore, I find that they will be unable to meet their burden of proof at trial and GRANT Abbott's motion for summary judgment.

SO ORDERED.

Ramon E. Reyes, Jr.
RAMON E. REYES, JR.
United States Magistrate Judge

Dated: May 22, 2017
Brooklyn, New York